**What types of studies does the NIH single IRB policy affect (new, existing, etc)?**

The policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subject’s research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

The policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018.  Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.  For contracts, the policy applies to all solicitations issued on or after January 25, 2018.  For the intramural program, the policy applies to intramural multi-site studies submitted for initial review on or after January 25, 2018. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

**What is a Reliance Agreement?**

A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more organizations engaged in human subjects research that permits one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subjects research activities for more than one site.

**What is the purpose of a reliance agreement?**

A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs are conducting the same multi-site research protocol. Once the agreement is executed, it can decrease the administrative burden and regulatory oversight of multiple institution’s IRBs.

**Can I use a reliance agreement at Lurie Children’s?**

Yes, Lurie Children's will allow other institutions to rely on Lurie Children’s as the IRB of Record (also known as the reviewing IRB) for a multi-site study and Lurie Children’s has also agreed to allow an external IRB to be the IRB of Record (rely on an external IRB).

Lurie Children’s tries to be flexible with how reliance is negotiated and documented and accepts it from several different sources, including

* + The SMART IRB Online Reliance System (see below)
  + The IREx Online System
  + Lurie Children’s template IAA form

**Who decides if Lurie Children’s will be the IRB of Record?**

**If the study is a network or consortium funded study, the network will often name the IRB of Record. For NIH funded studies, the lead PI may request his/her institution to be the IRB of Record; however, the institutional official (IO) makes the determination of whether the institution will serve as IRB or Record or not. All requests should be submitted to IRB office for consideration via email at IRBreliance@luriechildrens.org.**

**What is SMART IRB and can I use it for reliance at Lurie Children’s?**

SMART IRBis not an IRB; rather, it's a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for participating institutions and their investigators to request, track, and document study-specificreliance arrangements. Lurie Children’s is one of over 750 research organizations who are participating in SMART IRB.

Lurie Children’s prefers to utilize the [SMART IRB Master Common Reciprocal IRB Authorization Agreement](https://smartirb.org/) for reliance purposes. However, there may be some cases where a different reliance agreement will be negotiated. The IRB office will work with the Human Subject’s Protection representatives at participating sites to ensure the appropriate agreements are in place.

**I want to rely on an external IRB for my involvement in a multi-site protocol. Who decides whether I can do this?**

If the study is federally funded and/or there is a requirement for a single IRB, Lurie will agree to rely. If the study is not federally funded and single IRB review is not otherwise required, Lurie will review requests on a case by case basis.

Several factors are considered including whether the study is part of an existing network, consortium, or agency which encourages or mandates single IRB review; whether the proposed external IRB has already reviewed the study or a similar study; consideration of the IRB of record expertise (e.g., special subject population, atypical research design, sensitive topics); and efficiency considerations, especially for collaborating research. The reliance team will also review the protocol to assess the ability of Lurie Children’s to conduct study activities at Lurie Children’s and review the level of risk as determined by the IRB of Record.

**When (and how) should I submit a request for use of a Single IRB?**

**If Lurie Children’s will serve as the reviewing IRB for a multi-site study, that study must first be approved in Cayuse before relying sites can be added. Once the reliance agreements are executed, relying sites can be added on via modifications to the application.**

**If you wish for Lurie Children’s to rely on an external IRB, the reliance agreements must be executed with the reviewing organization (signed authorization agreement). The IRB office can assist with obtaining this document. In addition, you will need several documents from the reviewing IRB including the approved master protocol, approved consent/assent templates that will be modified to include local required Lurie Children’s language, and any other approved documents associated with the protocol. Once the agreement is reached and document is available, you may create a new study in Cayuse and proceed with the application.**

**The earlier you contact the IRB office the better we can assist you. Please email IRBreliance@luriechildrens.org.**

**I am applying for an NIH grant and want to comply with the NIH policy, where do I get started?**

**Contact the IRB office so we can assist in providing grant language describing the use of a Single IRB review process. Please contact** [IRBreliance@luriechildrens.org](mailto:IRBreliance@luriechildrens.org) **for assistance with this.**

**My grant is being renewed. How do I comply with the single IRB policy?**

The NIH policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018.  Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.  **Please email** [IRBreliance@luriechildrens.org](mailto:IRBreliance@luriechildrens.org) **for assistance.**

**Are there exceptions to the NIH single IRB review policy?**

**The NIH may grant exception if the use of a single IRB review is prohibited by federal, state, or tribal laws or regulations or where the use of a single IRB review is prohibited by established policy. The single IRB review policy also applies to domestic research sites only and does not apply to international sites.**

**Do Lurie Children’s and Northwestern University have the same IRB?**

No – Each organization has its own IRB, and Lurie Children’s IRB is not affiliated with Northwestern University. Lurie Children’s and NU are separate legal entities, operating under different federalwide assurances. For studies that involve Lurie Children’s and Northwestern University, a Master IRB Authorization Agreement is in place for Lurie Children’s to serve as the IRB of record. Please refer to the [Studies involving Lurie Children’s and Northwestern](https://www.luriechildrens.org/en/research/toolkit/irb-resources/studies-involving-lurie-childrens-and-northwestern/) page for instructions on how to submit these studies for review.

In situations in which both Lurie Children’s and NU are ceding review to an external IRB, NU must enter into a reliance agreement directly with the external IRB; NU cannot rely on the external IRB reliance/approval through Lurie Children’s.

**When Lurie Children’s will be the IRB of Record and I am the lead PI:**

***What are my responsibilities to Lurie Children’s IRB?***

**When serving as the lead PI and Lurie Children’s is the IRB of Record, you are responsible for contacting the IRB office as soon as possible so that the reliance process can begin with the relying site IRBs. The IRB office will aid in gathering appropriate local context information and can help you in submitting the appropriate information via Cayuse. You are responsible for submitting all study-related materials based upon Lurie Children’s policies and procedures, just as you would if you were conducting a single site research project at Lurie Children’s.**

**The study should be submitted in Cayuse as an initial application. Once approved by the Lurie Children’s IRB, modifications to add relying sites can be submitted. The IRB office will work with the study team and relying sites to customize local consent forms and other study documents and will issue site approval for each relying site.**

***What are my responsibilities to the relying sites?***

**You are responsible for communicating approvals to the relying site PIs, as well as providing the approved study materials (application, protocol, site consent form, approval letter, measures, etc.). You are also responsible for submitting any study related reports from relying sites to the Lurie Children’s IRB for review and approval. Essentially, you are submitting all sites’ study reports, revisions for local context, modifications, continuing reviews, reports of non-compliance, and adverse events as you would if you were conducting the study only at Lurie Children’s. The key difference is that you are now reporting for every site to Lurie Children’s IRB.**

***What information do I submit for the renewal?***

**At the time of renewal, you will submit a renewal application, along with all applicable renewal documents for ALL SITES approved by the Lurie Children’s IRB.**

***If another site experiences an unanticipated problem, what do I do?***

**Report the event to the Lurie Children’s IRB as soon as possible. The IRB office will facilitate review of this submission and communicate with the relying IRB. As Lead PI, you are agreeing to be responsible for reporting these events in accordance with Lurie Children’s IRB policies and procedures.**

***What do I do if a participating site needs to amend their study documents?***

**You will need to obtain the study documents from the local site and submit these materials as a modification to the Lurie Children’s IRB via Cayuse. Please consider whether the participating site’s revisions may also affect the other sites and make revisions, as necessary.**

***What do I do to amend the protocol and informed consent document for all sites?***

**Submit a modification to Lurie Children’s IRB via Cayuse with any revised documents.**

***How do I add a new site to an existing study that has been approved under single IRB review?***

**Submit a modification to add the site via Cayuse.**

**When Lurie Children’s is NOT the IRB of Record, but Lurie is a participating site and I am the PI:**

***Do I need to submit anything to the Lurie Children’s IRB when Lurie is approved as a site?***

**YES! You are required to submit an abbreviated application via Cayuse (select “Research Study Involving Human Subjects – External IRB Review” under Section 1 General Information where it asks “What Type of Submission is This?”). Even though another IRB has taken responsibility for the review of your research under the criteria required by the applicable federal regulations, there are still pieces of review that must occur at Lurie Children’s. The IRB also requests copies of the consent document(s), protocol, and IRB approval letter from the IRB of Record for documentation purposes. An acknowledgement letter will be provided via Cayuse once all documentation has been reviewed.**

***What local information do we put in the reviewing IRB’s informed consent document?***

**Lurie Children’s requires that parental permission, assent and adult consent forms include Lurie Children’s institutionally approved template language for subject injury and HIPAA authorizations as well as any other applicable institutional policy information (pregnancy testing for minors, for example). If you need assistance customizing the reviewing IRB’s consent form(s) to meet Lurie Children’s requirements, please contact the IRB office at IRBreliance@luriechildrens.org.**

***Do I need to submit anything to Lurie Children’s IRB at the time of renewal?***

**Yes, after receiving the approved and stamped study documents from the reviewing IRB, submit a renewal application in Cayuse that includes the stamped consent documents (if applicable) for the upcoming year, a copy of the approval letter from the IRB of Record, and any additional supporting materials related to enrollment at Lurie Children’s.**

**Please note – Cayuse will send out a notice of expiration based on the expiration date entered in Cayuse.** As long as the reviewing IRB approves the renewal before the studywide expiration date, research teams do not need to stop research activity, even if it shows “expired” in Cayuse (because Cayuse doesn’t know it’s been approved by the reviewing IRB until the study team submits the documentation to the Lurie Children's IRB to reset the date).

***What if an unanticipated problem occurs, what do I do?***

**Any adverse event or non-compliance with the protocol that takes place at Lurie Children’s should be reported via Cayuse as an Incident. This is to ensure that appropriate human subjects protections are in place, and to aid in compliance monitoring for the study and investigator.**

***What do I do if I need to amend the study documents?***

**The IRB of record must approve any modifications to study documents. Once those modifications have been approved by the reviewing IRB, please submit a Modification in Cayuse to inform the Lurie Children’s IRB of these changes. Acknowledgment of this modification will be sent via Cayuse once all changes have been incorporated.**

***What do I do if Lurie Children’s staff change?***

**Lurie Children’s remains responsible for ensuring all staff listed on a protocol, even one reviewed by another IRB, are appropriately trained in human subject’s research protections. As such, a modification should be submitted if new staff are to be added or removed. As with other personnel changes, approval of the modification must be granted before the individuals may begin work on the study. Local personnel changes can be handled by the Lurie Children’s IRB and do not need to be approved by the reviewing IRB.**

**NIH Single IRB Policy FAQs for the Research Community: https://www.aamc.org/download/474322/data/nihfaqsforsingleirb.pdf**